

REMARKS

Claims 1-94 were pending in the present application. Claims 15-17, 23-40, 54-56, and 66-81 have been withdrawn from consideration. No claims have been amended, added, or cancelled. Amendment and cancellation of certain of the claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Rejections under 35 U.S.C. § 112, ¶ 1

Claims 1-14, 18-22, 41-53, and 57-65—Written Description

Claims 1-14, 18-22, 41-53, and 57-65 stand rejected under 35 U.S.C. § 112, ¶ 1 for allegedly failing to comply with the written description requirement. In support of this rejection, the Office Action states that the, “claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The step of determining a treatment regime for applying at least one electrical burst to brain tissue before detecting an electrical activity in the brain is not describe[d] in the specification. The rejection is related to new matter.” Applicant disagrees with this rejection.

As noted in MPEP §2163.04, the burden of establishing a lack of written description falls on the Examiner. As explained in that section, the Examiner must present a preponderance of evidence to show why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims. That section goes on to specifically point out the express findings of fact that the Examiner must set forth in rejecting a claim for lack of written description. *Id.* As noted there, these findings should: (A) identify the claim limitation at issue; and (B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention. Applicant submits that the Examiner has failed to set forth a *prima facie* case for lack of written description.

The Office Action assertion that the rejection “relates to new matter” is insufficient. To be sure, word for word correspondence between the newly presented claim limitations and the original specification is not needed. It is sufficient that each claim limitation be expressly, implicitly, or inherently supported in the originally filed disclosure. *See* MPEP §2163.05. Applicant submits that the recitation of, “determining a treatment regime for applying at least one electrical burst to brain tissue before detecting an electrical activity in the brain tissue” is supported by the Applicant’s specification as filed, implicitly and inherently at the very least.

For example, on page 5, lines 17-19, the specification states, “[t]herefore different parameters for stimulation are better depending upon whether the burst is intended to provoke or terminate seizures.” The implication of this statement is that a treatment regime for applying a burst can be determined prior to detecting an electrical activity in the brain tissue, based on, for example, whether it is desirable to provoke or terminate seizures. That is, selection of a treatment regime may be based upon the desired outcome of such treatment, and be selected prior to, and independent of, the detection of any electrical activity. The specification goes on to provide example after example of various treatment regimes. For instance, treatment utilizing pulse-to-pulse interval variation, pulse amplitude variation, hyperpolarizing prepulse, pulse width variation, etc.

Inherent in the disclosure of the various treatment regimes is the fact that they can be determined prior to detecting an electrical activity in the brain tissue. Indeed, this point is made specifically, for example, in Applicant’s disclosure at page 9, which states that, “[i]n addition to producing bursts that contain intervals that are set in absolute time increments, this invention provides the improvement of setting pulse-to-pulse interval based upon the detected interval of the epileptiform activity as sensed on the electrodes in contact with the brain.” That is, in some variations, the pulse-to-pulse interval is constant and is not dependent upon the detection of brain electrical activity. It necessarily follows that such a treatment regime may be determined prior to the detection of any brain electrical activity.

Applicant submits that one having ordinary skill in the art at the time the application was filed would recognize that the inventor was in possession of the invention as recited in the

currently rejected claims. Accordingly, Applicant respectfully requests that the claim rejections based on lack of written description be withdrawn.

Claims 1-14, 18-22, 41-53, and 57-65—Enablement

Claims 1-14, 18-22, 41-53, and 57-65 stand rejected under 35 U.S.C. §112, ¶1 for allegedly failing to comply with the enablement requirement. In support of this rejection, the Office Action states that the, “claim(s) contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most-nearly connected, to make and/or use the invention. The step of determining a treatment regime for applying at least one electrical burst to brain tissue before detecting an electrical activity in the brain is not describe[d] in the specification. This rejection is related to enablement.” Applicant disagrees with this rejection.

The purpose of the enablement requirement is to ensure that the invention is communicated to the interested public in a meaningful way. *See* MPEP §2164. All that is needed to comply with this requirement is a specification that describes the invention in such a way that one having ordinary skill in the art would know how to make and use that which is defined by the claims. *Id.* Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. *Id.*

As described in detail above, the specification is replete with examples of various burst modalities. Determining a treatment regime for applying at least one electrical burst to brain tissue merely requires a selection of but one of them. Certainly one having skill in the art at the time of the invention would have the knowledge to make such a selection. Accordingly, Applicant respectfully requests that the claim rejections based on lack of enablement be withdrawn.

Allowable Subject Matter

The Office Action notes that claims 82-94 are allowable. Applicant submits that all pending claims are allowable and respectfully requests reconsideration and allowance of these claims in light of the remarks presented herein.

CONCLUSION

Applicant has, by way of the remarks presented herein addressed all issues that were raised in the outstanding Office Action. Applicant respectfully contends that this response has overcome the rejections and that the pending claims are in condition for allowance. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 459992000700.

Respectfully submitted,

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